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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,187	09/12/2003	Eric James Wall	CHM-005M	2186

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HASSE & NESBITT LLC
8837 CHAPEL SQUARE DRIVE
SUITE C
CINCINNATI, OH 45249

EXAMINER	
DESANTO, MATTHEW F	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/605,187	WALL, ERIC JAMES	
	Examiner	Art Unit	
	MATTHEW F. DESANTO	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-40,45 and 47-54* is/are pending in the application.

4a) Of the above claim(s) *12,18,23-27,31-35,37-40,45,47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11,13-17,19-22,28-30,36 and 49-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5, 7-11, 13-17, 19-22, 28-29, 30, 36, 49-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al. (USPN 6, 045, 534) and further in view of Flaherty et al. (USPN 7,303,549) and further in view of Ueda et al. (USPN 7,252,653) and Rise et al. (USPN 5,752,930).

Jacobsen et al. discloses an injection needle (22) that moves from multiple positions during use, a housing (12), a reservoir (18), a means for liquid communication (68+67), a means for inserting the injection needle (58+32), a means for pumping the medicament or urging means (20+16), a means for retracting the injection needle (23) that is on a diagram (18) that is adjusted by the air pressure that is released by the top cover hat interacts with the ball valve. Jacobsen et al. fails to teach the specific size of the needle, the specific flow rate and applying an adhesive to the device's housing.

Flaherty et al. discloses a delivery device with retraction means, injection means, and adhesive means that is an adhesive layer on the outer surface of the housing (Column 21).

Therefore, at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Jacobsen et al. with the teachings of

Flaherty because Flaherty discloses the benefit of using an adhesive layer on the housing since it allows for flexing of the skin during attachment and aids in the patients comfort (see Column 21 lines 54-65).

With regards to the other limitations not explicitly recited in the prior art are the flow rate and the size of the needle diameter. Both of these are well known variables that depend on the type of medication, size of the apparatus and form of treatment and are constantly modified depending on medical procedure. Therefore, it would have been obvious to modify the needle and flow rate of the prior art in order to fulfill the claim limitations since all the other limitations are present. Ueda et al. discloses the benefit of having needles with the specific claimed dimensions and Rise et al. discloses varying the flow rate from 1 micro liter per minute to 5000 micro liter per minute. Therefore, these references show how one of ordinary skill in the art would find it obvious to modify the prior art reference to the needle and flow rate in order to meet the needs of the infusion rate that is prescribed by the physician and thus fulfilling the claim requirements of applicant's invention since this would only take routine skill in the art.

Response to Arguments

3. Applicant's arguments with respect to the claims have been considered and are not persuasive.

4. Applicant argues that the examiner failed to follow Rule 1.104 “Nature of examination" because the examiner failed to show or describe the invention of the prior art and recite each and every claim.

5. The examiner would like to note that applicant fails to disclose the patentable subject matter of each independent claim and what the specific limitation is that overcomes the current rejection.

6. The examiner understands applicant's position but this was the reason for the summary of each reference and what was being relied upon. The Jacobsen reference was the primary reference teaching most of the claimed subject matter except the elements that were listed. The examiner tried to list each structural element that was recited in the Jacobsen reference that seemed complex or confusing. The examiner also tried to recite the teachings that were being relied upon by the secondary reference as well; by doing this, the examiner fulfills the requirements of Rule 1.104. If applicant still has questions then the examiner suggests contacting the examiner to discuss the rejection.

7. With regards to the 103, the examiner disagrees with the interpretation of the motivation to combine Jacobsen with Flaherty since Flaherty clearly discloses an added benefit. Also the device of Jacobsen is an injector applied to the outer skin and thus would be improved if an adhesive layer was applied to the injector especially since Flaherty discloses an expectation of an advantage when using an adhesive layer.

8. Applicant also argues that the references fail to teach a housing with a base for attachment to the skin, but this limitation is shown in Jacobsen since the base of Jacobsen attaches to the skin of the patient.

9. The use of the Ueda et al. and Rise reference show the level of skill in the medical art and thus the ability to use routine skill in the art to modify the needle size

and flow rate. Column 1 and 2, which were cited in the remarks section of the last reply are the main reason that one of ordinary skill in the art would understand and be able to use routine skill in the art to modify needle size since its common knowledge to experiment with the size and diameter of the needle especially when using different types of medications. Rise teaches that certain medications require specific flow rates and that carefully consideration must be given during these times (column 1, line 24-31). Rise also discloses in claim 11 the flow rate of the first time period being 1 microliter to 5000 microliter per minute. Therefore the examiner concluded that one of ordinary skill in the art would be able to modify the flow of the prior art by using routine experimentation to overlap the range given in the claimed invention. The examiner would also like to note that the primary reference fails to disclose the specific flow rate claimed but is unsure whether the flow rate of Jacobsen would be different since all the structural limitations are the same.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto
/Matthew F DeSanto/
Primary Examiner, Art Unit 3763